

### **Rejections Under 35 USC § 101**

Claims 1-17 are rejected because the claimed invention is not supported by a specific asserted utility, well established utility or a substantial utility. The Examiner contends that although utilities are asserted the specification, they are not specific to the isolated DNA molecule comprising the DNA sequence of SEQ ID NO:1.

The Examiner contends that the utility of the isolated DNA molecule is based on the assertion that it encodes a sequence which has homology to the Wnt binding domain of the extracellular binding domains of the Frizzled/Frazzled family of proteins. The Examiner contends that there is no teaching of which of the more than a dozen Wnt proteins the encoded product of SEQ ID NO:1 would be capable of binding or which receptor binding interactions SDF-5 would be capable of regulating.

The Examiner points out that the human SDF-5 expression pattern differs from the murine homologue. The Examiner contends that even if SDF-5 is an SDF-5 protein or a Frizzled/Frazzled protein it cannot be predicted what the protein does. The Examiner states that there is no teaching of a relationship to any specific disease and that to determine "real world use" additional experimentation is required and finally that the specification essentially gives an invitation to experiment.

Applicants assert that the invention is supported by a specific utility or a substantial activity. With respect to lack of utility, the PTO is required to establish a *prima facie* case. In re Brana, 34 U.S.P.Q.2d 1436, 1440-1441 (Fed. Cir. 1995). Under the Utility Examination Guidelines, published July 14, 1995, the Patent Office bears the burden of *prima facie* proof that no credible utility has been asserted for the claimed invention. As defined in the Guidelines, the PTO is required to "establish that it is more likely than not that a person skilled in the art would not consider credible any specific utility asserted by the applicant for the claimed invention (emphasis supplied)." The PTO has failed to meet its burden to establish a *prima facie* case of unpatentability.

Applicants provide the nucleotide sequence of human SDF-5 and the protein encoded, and methods of making human SDF-5 polypeptides using the DNA sequences. In addition, Applicants have provided art-recognized credible uses of SDF-5 proteins. As the Examiner recognizes, the specification discloses utilities for SDF-5 including inducing formation/growth differentiation proliferation and/or maintenance of chondrocyte and /or cartilage tissue. In addition the examiner recognizes that the protein encoded by SEQID NO:1 is useful for binding Wnt protein and thus regulating the interaction of Wnt genes to receptor proteins. The asserted utility is based on the fact that the molecule of SEQ ID NO:1 encodes a sequence which has homology to the Wnt binding domain of the extracellular binding domains of the Frizzled/Frazzled family. Thus, the skilled artisan can readily both make and use the SDF-5 proteins of the present invention without undue experimentation.

Furthermore, following Applicants' disclosure of methods of making SDF-5, activity assays for SDF-5, the skilled artisan can readily determine the *in vivo* activities of Applicants' disclosed protein without undue experimentation. Thus, Applicants have provided a novel member of a well-recognized class of compounds with known activities: the Frazzled family of proteins. It is well known to those skilled in the art that members of the this family are capable of activities including inducing formation/growth differentiation proliferation and/or maintenance of chondrocyte and /or cartilage tissue. Thus, there is no question that the skilled artisan would consider Applicants' disclosed utilities of SDF-5 to be specific or substantial.

### **Rejections Under 35 USC § 112**

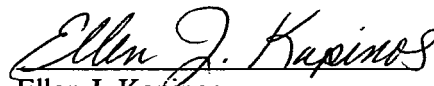
Claims 1-17 are rejected because the Examiner contends, one skilled in the art, for the reasons set forth in the §101 rejection described above, would not know how to use the claimed invention. Applicants assert that for the reasons Applicants have set forth above, the claimed invention is supported by a specific utility and therefore one skilled in

the art would know how to use the claimed invention.

### CONCLUSION

In view of the foregoing remarks, Applicants respectfully request reconsideration and withdrawal of the rejections of record and issuance of the claims as amended. Should the Examiner believe that a telephonic interview would assist in clarifying any remaining issues, or to otherwise expedite prosecution, Applicants respectfully invite the Examiner to call the undersigned attorney at the telephone number provided below. If any fee is due with regard to this paper, Applicants hereby authorize payment of such fee from Deposit Account No. 07-1060.

Respectfully submitted,



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